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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/035,324

01/04/2002

H. William Bosch

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06/20/2006

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EXAMINER

HAGHIGHATIAN, MINA

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/035,324

Applicant(s)

BOSCH ET AL.

Examiner

Mina Haghighatian

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 15-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/11/06 has been entered.

Receipt is also acknowledged of amendments and Remarks filed on 02/28/06. Accordingly claims 1-34 remain pending, of which claims 15-34 are withdrawn. Thus claims 1-14 are under examination.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiedmann et al (5,747,001) in view of Tabibi et al (6,682,758).

Wiedmann et al teach aerosols containing droplets of an aqueous dispersion of nanoparticles of insoluble beclomethasone particles having a surface modifier on the surface thereof. A suitable surfactant is tyloxapol (see col. 4, lines 49-60), the particles are preferably less than 400 nm in size, or more preferably less than 250 and most

Art Unit: 1616

preferably less than 100 nm in size (see col. 6, lines 8-15 and col. 10, lines 25-35). The process of making such nanoparticles includes attrition and filtration (see col. 7, lines 18-21). Wiedmann lacks teachings on sterile filtration.

Tabibi et al teach water-insoluble drug delivery systems comprising a water-insoluble drug, a water-miscible organic solvent and a surfactant. Surfactants form vesicles having an average particle size of about 50-200 nm (see col. 3, lines 30-36 and col. 7, lines 30-35). The formulations can be used as an aerosol (see col. 4, lines 6-10). The said formulations are sterilized by passing each solution through a sterilizing membrane filter. The filter is a 0.22 micron pore rated sterile filter (see col. 7, lines 45-49 and col. 8, lines 1-16).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have implemented the sterile filtration as taught by Tabibi in the formulations and process of Wiedmann, since Wiedmann teaches filtration of a nanoparticles of beclomethasone and tyloxapol. In other words, one of ordinary skill in the art would have been motivated to implement sterile filtration of Tabibi instead of simple filtration of Wiedmann because sterilization of formulations is beneficial to recipients.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiedmann et al (5,747,001) in view of Osbakken et al (2002/0061281).

Wiedmann et al teach aerosols containing droplets of an aqueous dispersion of nanoparticles of insoluble beclomethasone particles having a surface modifier on the surface thereof. A suitable surfactant is tyloxapol (see col. 4, lines 49-60), the particles are preferably less than 400 nm in size, or more preferably less than 250 nm and most preferably less than 100 nm in size (see col. 6, lines 8-15 and col. 10, lines 25-35). The process of making such nanoparticles includes attrition and filtration (see col. 7, lines 18-21). Wiedmann lacks teachings on sterile filtration.

Osbakken teaches aerosolized anti-infectives and anti-inflammatories for the treatment of sinusitis. The process of preparing the formulations includes weighing and measuring each ingredient, adding the ingredients together, mixing with dilutents such as sterile water and filtering with a coarse filter and then a fine filter such as a 0.22 micron filter (see [0104], [0171], [0176], [0198] and [0199]). The steroidal anti-inflammatories include beclomethasone and budesonide (see [0139]).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have implemented the sterile filtration as taught by Osbakken et al in the formulations and process of Wiedmann, since Wiedmann teaches filtration of nanoparticles of beclomethasone and tyloxapol. In other words, one of ordinary skill in the art would have been motivated to implement sterile filtration as taught by Osbakken et al instead of simple filtration of Wiedmann et al because sterilization of formulations is beneficial to recipients.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiedmann et al (5,747,001) in view of Saidi et al (6,241,969).

Wiedmann et al teach aerosols containing droplets of an aqueous dispersion of nanoparticles of insoluble beclomethasone particles having a surface modifier on the surface thereof. A suitable surfactant is tyloxapol (see col. 4, lines 49-60), the particles are preferably less than 400 nm in size, or more preferably less than 250 nm and most preferably less than 100 nm in size (see col. 6, lines 8-15 and col. 10, lines 25-35). The process of making such nanoparticles includes attrition and filtration (see col. 7, lines 18-21). Wiedmann lacks teachings on sterile filtration.

Saidi et al teaches aqueous compositions comprising corticosteroids and a surfactant in a delivery vehicle for pulmonary or nasal administration. The suitable steroids include beclomethasone dipropionate (see col. 6, lines 8-30). Examples 1-5 teach the process of making the said formulations which includes sterilizing the formulation by passing the diluted corticosteroid composition through a 0.22 micron sterile filter.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have implemented the sterile filtration as taught by Saidi et al in the formulations and process of Wiedmann, since Wiedmann teaches filtration of

Art Unit: 1616

nanoparticles of beclomethasone and tyloxapol. In other words, one of ordinary skill in the art would have been motivated to implement sterile filtration as taught by Saidi et al instead of simple filtration of Wiedmann et al because sterilization of formulations is beneficial to recipients.

Response to Arguments

Applicant's arguments with respect to claims 1-14 have been considered but are moot in view of the new ground(s) of rejection.

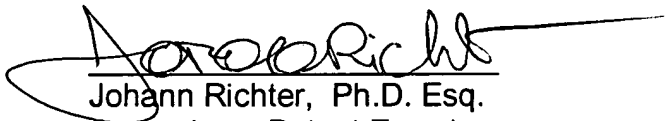
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1616

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mina Haghighatian
June 07, 2006


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